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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,200	09/04/2001	Anthony J. Bradshaw	005618.P2306CD	2584

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EXAMINER	
LACYK, JOHN P	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
07/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/944,200	BRADSHAW ET AL.	
	Examiner	Art Unit	
	John P. Lacyk	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-22,24,26-28,30-44,46-59,61,62,64,65,67,74 and 75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22,24,26-28,30-44,46-59,61,62,64,65,67,74 and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 24, 28, 33, 35, 38-41, 44, 48, 54 and 61-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for centering the radiotherapy lumen within the vessel, does not reasonably provide enablement for the longitudinally channeled, fluted, segmented or scalloped balloon being the means for the centering. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. On page 18, the specification states that segments or scallops may be used to permit flow by of blood. There is no teaching of using an inflatable balloon catheter having such segments to center the device or that the segments or scallops are critical to centering the device.

3. Claims 28, 33, 38, 40, 44, 48, 54, 61-62, 64-65, 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 67 recites language directed to the centering catheter, when deployed, does not dilate the lumen of the duct, however there appears to be no support in the specification directed to such language. The specification does not anywhere discuss the lumen not being dilated when the centering device is deployed.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 28, 30-41, 44, 47, 54, 59, 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weikl (9102312.2) in view of Blackshear, Jr. et al (5,308,356). Weikl discloses a method of treating the wall of a blood vessel by inserting a catheter into the vessel lumen until the balloon is adjacent the target, inflating the balloon to substantially center the radiotherapy lumen (Figure 2), advancing the radioactive source to the treatment region and withdrawing the source after a predetermined interval of time for the therapy. Weikl discloses the claimed method except for allowing perfusion of the blood past the inflated balloon through channels in the balloon. Blackshear, Jr. et al discloses a balloon catheter used for angioplasty and teaches that it is well known to provide a channeled balloon having grooves (36) to allow for the perfusion of blood past an inflated balloon catheter during the angioplasty procedure. Therefore a modification of the method of Weikl to include a perfusion path through channels in the balloon would have been obvious since this would allow the procedure to continue without being interrupted to deflate the balloon and allow blood to pass. The grooves are considered to also include channels, flutes and scallops, which are similar terms for the same structure. With respect to claims 21, 27, 32 and 59 to select any well known radioactive source with specific radiation dosages would have been obvious to one skilled in the art

based upon the its suitability for the intended use. Since different radioactive sources are known to provide different doses and different areas of the body may need specific dose range to select the specific radiation material to provide a specific radiation dosage would have been obvious to one skilled in the art based upon which material would be more suitable for the intended use.

6. Claims 48, 51-53, 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weikl in view of Blackshear, Jr. et al as applied to claims above, and further in view of Van't Hooft et al (4,881,937).

Weikl in view of Blackshear, Jr. et al discloses the claimed method except for the use of an afterloader having a dummy wire to determine the proper placement of the radioactive wire. Van't Hooft et al teaches that it is well known to use such an afterloader having a dummy wire to aid in proper placement of the radioactive source. Therefore a modification of Weikl such that the device is used with an afterloader and dummy wire would have been obvious in view of the teachings of Van't Hooft et al.

7. Claims 19, 21-22, 24, 27, 61-62, 64-65 and 74-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weikl in view of Blackshear, Jr. et al and Malinowski et al (5,660,180).

Weikl and Blackshear, Jr. et al, as discussed above, teaches the use of a segmented, channeled or scalloped balloon and a modification would have been obvious for the same reasons as discussed above

Weikl discloses the claimed invention except for the catheter being inserted or advanced over a guidewire that has previously been inserted. Malinowski et al teaches that it is well known to use the aid of a guidewire for inserting a catheter and the guidewire being inserted first and the balloon catheter being inserted over the guidewire to guide the catheter to the desired area in the body. Therefore a modification of Weikl to use a guidewire to aid in inserting or advancing the catheter of Weikl to the proper place would have been obvious in view of the teachings of Malinowski et al since the use of guidewires to aid in inserting catheters is well known because of the tortuous path the catheter takes through a blood vessel the use of a guidewire makes the insertion of the catheter easy to guide into and through the body to the desired position, therefore the modification would have been obvious to one skilled in the art to allow for easier insertion of the catheter.

8. Claims 20, 26, 42-43, 46, 49-50, 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weikl in view of Malinowski et al and Blackshear, Jr. et al as applied to claims above, and further in view of Flexmedic article.

Weikl discloses the claimed method except for the guidewire for inserting the radioactive source being made from a super-elastic material. Flexmedics discloses the use of Nitinol which is a well known shape memory alloy that has superelastic properties and teaches that it is well known to use such a material with guidewires. Therefore a modification of Weikl such that the wire used to insert the radioactive

source is made from Nitinol would have been obvious since this would have been the mere substitution of one well known guidewire material for another.

9. Applicant's arguments filed 04/18/07 have been fully considered but they are not persuasive. Applicant argues that paragraph [0053] provides support for the channeled, fluted, segmented or scalloped balloon being the centering means for centering. However the examiner's position is that this paragraph only provides support for the channeled, fluted, segmented or scalloped portion to "permit some flow-by of blood sufficient to avoid complete blockage during treatment" and in no way recites that the centering is accomplished because of the channels, etc. While the balloon itself centers the source it does not specifically recite that it is the shape of the balloon that centers, such segments are only disclosed as permitting blood flow. Even if there were no segments to allow blood flow the balloon would still center the source.

10. Applicant further argues that while the specification does not explicitly disclose the limitation of "without dilating the lumen (or the duct or the vessel or said/the target site)" it is an inherent feature of the balloon. Firstly the examiner disagrees with such a statement, while the lobes may not inflate as much when they come in contact with the vessel wall and allow for the remaining lobes to inflate, it is not an inherent feature of any balloon. How the balloon inflates would depend on many different parameters what the balloon is made of, how thick the balloon is, how much pressure is used to inflate the balloon (once all of the lobes are inflated if there was still a positive pressure the balloon would continue to expand thus dilating the lumen). Therefore it appears that

whether the lumen would dilate or not is not an inherent feature of a balloon catheter but relies on many different parameters and since the specification does not clearly state this the rejection is still deemed to be proper. Further if it were to be an inherent feature then the prior art balloons having "lobes" would also provide this "inherent" feature.

11. Applicant argues that Weikl teaches a radioactive source is centered by a "fixed" lumen and does not substantially center the radiotherapy lumen. The examiner's position is that the Weikl device would inherently center the radiotherapy lumen when it is inflated, as discussed in the rejection and as shown in Figure 2 and further in view of the modification of Weikl to include channels or segments of Blackshear to allow for blood flow, in view of applicant's argument that balloons with lobes would inherently center the radiotherapy lumen, the modification would then inherently provide such a centering means. Applicant further argues that there is no motivation to combine Weikl and Blackshear and that one would not look to Blackshear to teach an alternative means for performing the same function i.e. centering a radiation source. However there is proper motivation to combine, as discussed in the rejection, Blackshear was used to provide a teaching of a balloon catheter having channels or segments to allow blood flow such that a procedure could be performed without having to interrupt it to deflate the balloon to allow blood to flow and one skilled in the art would clearly be motivated to make such a modification of Weikl to allow the procedure to be performed without having to interrupt the procedure to allow blood to flow.

12. Applicant argues with respect to the rejection over Weikl in view of Blackshear and Van't Hooft that there is no motivation to combine the references. The combination

of Weikl and Blackshear has been discussed above. With respect to Van't Hooft, Van't Hooft provides a teaching of using a dummy wire with an afterloader such that the proper location can be determined first (with the dummy wire) in order to reduce unwanted exposure of the radioactive source to the body. The dummy wire is used to locate the proper position first and then the radioactive wire is advanced, to the now known position, thus reducing the time the radioactive source is in the body prior to the radiotherapy treatment. Therefore one would clearly be motivated to modify Weikl to use such a dummy wire to reduce any unwanted radioactive exposure.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is 571-272-4728. The examiner can normally be reached on Mon-Fri, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

John P Lacyk
Primary Examiner
Art Unit 3735

J.P. Lacyk